IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

BAILEY SILVERMAN and LOUIS SILVERMAN	§	
Plaintiffs	§	
V.	§	CASE NO. 4:10-cv-1952
WATSON LABORATORIES, INC.---, FLORIDA WATSON PHARMA, INC. and CAPSUGEL, INC.	§	
Defendants.	§	

PLAINTIFFS' SECOND AMENDED COMPLAINT

Plaintiffs Bailey Silverman and Louis Silverman, by and through the undersigned counsel, allege as follows:

THE PARTIES

1. Plaintiff Bailey Silverman and her husband, Plaintiff Louis Silverman, M.D., reside in Houston, Texas. This lawsuit is filed because Bailey Silverman was poisoned by arsenic contained in defective prescription blood pressure drug capsules that were manufactured, sold, and/or distributed by Defendants.

2. Defendants Watson Laboratories, Inc.---Florida and Watson Pharma, Inc. (collectively "Watson") are manufacturers and sellers of, among other things, prescription drugs. Watson has already been served in this action.

3. Defendant Capsugel, Inc. ("Capsugel") is manufacturer and seller of, among other things, gelatin capsular covers/capsules. Capsugel may be served with process by serving process on Fred Cooley, Vice President of Operations, Capsugel, Inc., 535 N. Emerald Rd., Greenwood, SC 29646. Capsugel recently was designated as a "responsible third party" by

Watson pursuant to Texas Civil Practice & Remedies Code § 33.004. Plaintiffs timely file this Second Amended Complaint pursuant to Texas Civil Practice & Remedies Code § 33.004 adding Capsugel as a defendant.

JURISDICTION

4. Defendants conduct business and are subject to personal jurisdiction in this state and county. At all times relevant, Defendants were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Texas, either directly or indirectly through third parties or related entities, the prescription drug Taztia XT capsules and/or related drugs (hereinafter "Taztia"), and/or its component capsular covers.

5. This Court has jurisdiction and venue over this action because Defendants conduct business and/or are subject to personal jurisdiction in this county and because a substantial part of the events giving rise to this claim occurred in this county. Capsugel sold Watson defective and dangerous capsular covers that contained arsenic. Watson then incorporated the defective and dangerous capsular covers into its Taztia capsules. Plaintiff Bailey Silverman, a resident of the State of Texas, Harris County, later ingested the dangerous and defective Taztia capsules. Plaintiffs suffered severe injuries in Harris County, Texas as a result of Plaintiff Bailey Silverman's ingestion of the dangerous and defective Taztia capsules.

FACTS

6. Taztia (also known as Dilitiazem) is a prescription drug in a class of medications called calcium channel blockers, that are commonly prescribed to treat high blood pressure and prevent chest pain.

7. Watson is a global pharmaceutical company with approximately $3 billion in revenues. Watson sells a wide variety of pharmaceutical products, including Taztia.

8. Capsugel is a global company that sells and manufactures gelatin and non-gelatin capsules. Capsugel provides empty capsules, as well as formulations, for both pharmaceuticals and dietary supplements. Capsugel manufactured and sold empty gelatin capsular covers/capsules to Watson. Watson then used the Capsugel capsular covers/capsules in its manufacture of Taztia capsules. Watson filled the Capsugel capsules with various ingredients to manufacture its Taztia capsules. Watson then packaged the Taztia capsules and placed them in the stream of commerce.

9. Arsenic is a well known and deadly poison. There is no medical or therapeutic reason for arsenic to be present in any blood pressure medication or the capsulular covers for such medication. Arsenic is deadly, and arsenic poisoning can cause a variety of severe, painful, permanent, and debilitating conditions.

10. Watson's production of a blood pressure medication that contains arsenic has subjected numerous individuals to grave danger, and, in this case, severely injured Plaintiff Bailey Silverman. Indeed, because (as discussed below) arsenic poisoning is so difficult to diagnose, many others may have been injured or killed or may be injured in the future by Defendants' products without ever knowing the source of the injury and without receiving adequate medical care as a result.

11. Although the products sold by Defendants were dangerous and defective, Defendants represented, among other things, that their products were safe and effective for their intended use, and that their products did not contain a known and deadly contaminant.

12. The Taztia capsules, including their capsular covers, were defective in their manufacture. Defendants also failed to act prudently in their roles in the procurement of safe materials, manufacture, distribution and sale of Taztia capsules, including their capsular covers, including, but not limited to, failing to adequately test, monitor, and/or inspect the raw ingredients and/or component parts of capsules and their capsular covers, which caused adulterated Taztia to be distributed and given to patients, causing injuries like the ones sustained in this case.

13. The component capsular covers and final product Taztia capsules were defective at the time each was placed in the stream of commerce.

14. Defendants knew or should have known that the capsular covers and Taztia capsules were defective at the time the products left each manufacturer's respective control and custody.

15. Defendants also knew or should have known that the Taztia capsules and/or their component capsular covers were causing adverse reactions to consumers.

16. Notwithstanding their knowledge, Defendants continued (and apparently continue to this very day) to supply and sell the capsular covers and/or Taztia capsules without providing any warnings about the risks and dangers associated with the products to members of the public and the medical community, and without taking action to prevent arsenic-containing products from reaching consumers.

17. As a direct and proximate result of Plaintiff Bailey Silverman's consumption of defective Taztia capsules, Plaintiff Bailey Silverman has been severely and permanently injured and incurred substantial damages, including, but not limited to, past and future medical, hospital, and other expenses, loss of income, physical and mental pain and suffering, loss of enjoyment of life, and other damages for which Defendants are liable.

18. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs. Each defendant is independently responsible for the defective manufacture of the products.

FACTS REGARDING PLAINTIFF BAILEY SILVERMAN

19. Plaintiff Bailey Silverman lives in Houston, Texas with her husband Louis Silverman, MD. In late 2008, after switching from another blood pressure medication, Mrs. Silverman was prescribed and purchased Watson's Taztia capsules. After she began taking Watson's Taztia capsules, she then began to experience a number of progressive symptoms, including weakness, numbness and tingling, loss of motor skills, constant pain in the extremities, painful spasms in the face, and difficulty breathing. Ultimately, Mrs. Silverman presented to St. Luke's Episcopal Hospital in Houston, Texas, in a life threatening condition, and was diagnosed with dangerously high levels of arsenic poisoning.

20. Arsenic poisoning can be very difficult to diagnose, and, for that reason, the signs and symptoms are often mistaken for other medical conditions, such as Bell's palsy, stroke, or other neuropathy. If left untreated, arsenic poisoning is almost universally fatal. If not for the timely diagnosis made and treatment and care provided by her physician, Mrs. Silverman likely would have died.

21. As a result of being poisoned with arsenic, Mrs. Silverman had to undergo chelation therapy. Chelation therapy carries with it significant risks, including the risk of anaphylactic shock or death. Mrs. Silverman was hospitalized for almost a month for this therapy and extensive medical treatment. She endured significant and almost constant pain.

22. Even after being discharged from the hospital, Mrs. Silverman continues to suffer from debilitating and permanent aftereffects of her arsenic poisoning.

23. The reason that Mrs. Silverman had dangerously elevated levels of arsenic in her blood has since been confirmed. The Taztia capsules she was taking that were sold by Watson contained arsenic.

24. As a direct and proximate result ingesting the defective Taztia capsules, Plaintiff Bailey Silverman has been injured and incurred substantial damages, including, but not limited to, substantial medical and hospital expenses, loss of income, severe physical and mental pain and suffering, loss of enjoyment of life, severe, permanent and ongoing resulting injuries, and medical and other expenses that likely will be incurred in the future and other damages for which Defendants are liable. Defendants are independently liable for Plaintiffs' injuries under each of the causes of action specified below.

25. Further, Defendants, upon information and belief, have or may have failed to comply with federal standards applicable to the sale of drugs and their components including, but not limited to, one or more of the following violations:

    a. The Taztia capsules and/or their component capsular covers were adulterated pursuant to 21 U.S.C. § 351 because, among other things, Defendants failed to meet established performance standards, and/or the methods, facilities, or controls used for the products' manufacture, packing, storage or installation were not in conformity with federal requirements. *See* 21 U.S.C. § 351.

    b. The Taztia capsules were adulterated pursuant to 21 U.S.C. § 351 because, among other things, their strength differed from or their quality or purity fell below the standard set forth in the official compendium for Taztia, and such deviation is not plainly stated on Watson's label.

    c. Defendants violated 21 C.F.R. § 210.1 because the process by which the Taztia capsules and/or their component capsular covers were manufactured, processed, and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that it meets the requirements as to safety and has the identity and strength and meets the quality and purity characteristics that it purposes or is represented to possess.

d. Defendants violated 21 C.F.R. § 211.165 because the test methods employed by Defendants were not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented.

e. Defendants violated 21 C.F.R. § 211.165 in that the Taztia capsules and/or their component capsular covers failed to meet established standards or specifications and any other relevant quality control criteria.

f. Defendants violated 21 C.F.R. § 310.303 in that the Taztia capsules and/or their component capsular covers were not safe and effective for their intended use.

COUNT ONE
Strict Liability

26. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege on information and belief as follows.

27. At all times relevant to this action, Defendants were the manufacturers, sellers, and/or suppliers of defective Taztia capsules and/or their component capsular covers and placed them into the stream of commerce.

28. The Taztia capsules and/or their component capsular covers were expected to and did reach Plaintiff Bailey Silverman without substantial change in the condition in which they were manufactured and sold.

29. The Taztia capsules and/or their component capsular covers and were defectively manufactured at the time that they left each defendant's control, in that they contained arsenic, a deadly poison.

30. The Taztia capsules and/or their component capsular covers were unsafe for normal or reasonably anticipated use.

31. The Taztia capsules and/or their component capsular covers were unreasonably dangerous in that they were unsafe when used for the intended purpose for medical treatments to consumers.

32. The Taztia capsules and/or their component capsular covers were more dangerous than an ordinary consumer or physician would expect, and the foreseeable risk of injuries from their administration exceeded their associated benefits.

33. Defendants wrongfully permitted defective products to be placed into the stream of commerce, in, among others, the following ways:

a. Defendants failed to exercise reasonable care in the manufacture of their products;

b. Defendants failed to exercise reasonable care in the selection, inspection or testing of their suppliers, supplies, raw materials, component parts, products and/or their ingredients;

c. Defendants failed to exercise reasonable care in the packaging of their products;

d. Defendants failed to provide any or adequate warnings about the risks and dangers associated with the use of their products;

e. Defendants failed to completely, accurately and in a timely fashion, disclose the adverse event reports associated with the use of their products;

f. Defendants failed to recall, withdraw, and remove their defective products or component parts from the market once they knew or should have known of the risks and dangers associated with the use thereof;

g. Defendants failed to promptly respond to data, reports, and publications describing problems associated with their products by conducting adequate analysis, testing, and surveillance;

h. Defendants failed to implement pre-marketing and post-marketing measures to identify problems and to notify and warn physicians, medical providers, and other members of the medical community, of the risks and dangers associated with the use of the their defective products, and to recall the defective products;

i. Defendants failed to adequately and reasonably establish, maintain, and comport with acceptable quality control mechanisms to prevent defective products from entering the marketplace or from using unsafe component parts and/or raw materials;

j. Defendants failed to comply with and conform to all applicable legal, regulatory, and administrative approval, licensing, and import requirements for their defective products and their component parts.

34. Plaintiff Bailey Silverman could not, through the exercise of reasonable care, have discovered the defects or perceived the dangers posed by the Taztia capsules.

35. As a direct and proximate result of Plaintiff Bailey Silverman's ingestion of the defective Taztia capsules, Plaintiff has been injured and incurred the substantial damages discussed above.

36. Defendants' conduct was committed with malice, gross negligence, recklessness and/or knowing, conscious, wanton, willful, and/or deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff Bailey Silverman, thereby entitling her to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

COUNT TWO
Breach of Implied Warranty

37. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege on information and belief as follows.

38. Prior to the time that the contaminated Taztia capsules were ingested by Plaintiff Bailey Silverman, Defendants impliedly warranted that the Taztia capsules and/or their component capsular covers were of merchantable quality and safe for the use for which they were intended.

39. Plaintiff Bailey Silverman and her medical providers relied upon the skill, judgment, and representations of Defendants. The Taztia capsules and/or their capsular covers were unsafe for their intended use and were not of merchantable quality as warranted by

Defendants in that they had dangerous propensities when put to their intended use, could cause severe injury to the user, and did in fact cause such injury.

40. As a direct and proximate result of her ingestion of the dangerous and defective Taztia capsules and/or their capsular covers, Plaintiff Bailey Silverman has been injured and incurred substantial damages discussed above.

41. Defendants' conduct was committed with malice, gross negligence, recklessness and/or knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety to patients/consumers, including Plaintiff Bailey Silverman, thereby entitling Plaintiff Bailey Silverman to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

COUNT THREE
Negligence

42. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege on information and belief as follows.

43. Defendants owed a duty to exercise reasonable care in the design, manufacture, testing, inspection, marketing, distributing, sale, and/or post-sale surveillance of the Taztia capsules and/or their component parts, including the Taztia capsules ingested by Plaintiff Bailey Silverman, so that they could be safely used for the purpose for which they were intended, or in a reasonably foreseeable manner.

44. This duty included the duty not to introduce dangerous and unfit products into the stream of commerce that caused users to suffer from unreasonable, dangerous, or untoward adverse side effects.

45. In breach of their duty of care, Defendants were negligent in the manufacture, testing, distribution, inspection, marketing, sale, and/or post-sale surveillance of the Taztia capsules and/or their component capsular covers, including the following ways:

a. Defendants failed to exercise reasonable care in the manufacture of the Taztia capsules and/or their component capsular covers;

b. Defendants failed to exercise reasonable care in the selection or inspection of their suppliers, supplies, raw materials, component parts, products and/or their ingredients;

c. Defendants failed to exercise reasonable care in the packaging of their products;

d. Defendants failed to provide any or adequate warnings about the risks and dangers associated with the use of their products;

e. Defendants failed to completely, accurately and in a timely fashion, disclose the adverse event reports associated with the use of their products;

f. Defendants failed to recall, withdraw, and remove their defective products from the market once they knew or should have known of the risks and dangers associated with the use thereof;

g. Defendants failed to promptly respond to data, reports, and publications describing problems associated with the Taztia their products by conducting adequate analysis, testing, and surveillance;

h. Defendants failed to implement pre-marketing and post-marketing measures to notify and warn physicians, medical providers, and other members of the medical community, of the risks and dangers associated with the use of their products, and to recall the defective products;

i. Defendants failed to adequately and reasonably establish, maintain, and comport with acceptable quality control mechanisms to prevent defective products from entering the marketplace or from using unsafe contents, component parts, raw materials, and/or ingredients;

j. Defendants failed to comply with and conform to all applicable legal, regulatory, and administrative approval, licensing, and import requirements for the Taztia capsules and/or their capsular covers and/or their component parts;

k. Defendants were otherwise negligent and careless.

46. Defendants knew or should have known that consumers such as Plaintiff Bailey Silverman would foreseeably suffer injury as a result of their failure to exercise ordinary care as described above.

47. The Taztia capsules were expected to and did reach Plaintiff Bailey Silverman without substantial change in the condition as designed, manufactured, marketed, distributed, and sold, prior to their administration to Plaintiff Bailey Silverman, who used the Taztia capsules as intended, or in a reasonably foreseeable manner.

48. Defendants' negligent conduct caused substantial harm to Plaintiff Bailey Silverman.

49. As a direct and proximate result, Plaintiff Bailey Silverman has been injured and incurred substantial damages as discussed above.

50. Defendants' conduct was committed with malice, gross negligence, recklessness and/or knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety to patients/consumers, including Plaintiff Bailey Silverman, thereby entitling Plaintiff Bailey Silverman to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

COUNT FOUR
Loss of Consortium

51. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows.

52. As a direct and proximate result of Defendants' defective product, the acts and omissions described herein, and the resulting severe and debilitating injuries sustained by Plaintiff Bailey Silverman, Bailey and Louis Silverman have suffered the loss of services, loss of financial support, loss of society including loss of companionship, care, assistance,

attention, and mental anguish, entitling them to compensatory and punitive damages and attorney's fees.

COUNT FIVE
Punitive or Exemplary Damages

53. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege on information and belief as follows.

54. The evidence will show that the conduct of some or all Defendants was such that it warrants the imposition of punitive or exemplary damages.

JURY DEMAND

Plaintiffs demand a jury trial and have tendered the appropriate jury fee.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, as follows:

A. For an award of compensatory damages, including damages against Defendants for past and future medical, hospital and other expenses, past and future loss of income, pain, suffering and mental anguish, loss of consortium, and other damages according to proof at trial;

B. For an award of punitive or exemplary damages against Defendants;

C. For reasonable attorneys' fees and costs;

D. For pre-judgment interest; and

E. For such further and other relief the court deems just, equitable, and proper.

Dated: November 17, 2011.

Respectfully Submitted,

Williams, Kherkher, Hart Boundas LLP

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Certificate of Service

This is to certify that on the 17th day of November, 2011, I electronically filed the foregoing document with the Clerk of the Court for the U.S. District Court, Southern District of Texas, using the electronic case filing system of the Court. The electronic case filing system sent a "Notice of Electronic Filing" to the following attorney of record that has consented in writing to accept this Notice as service of this document by electronic means:

Michael A. Walsh – via electronic

John T. Boundas